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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,436	12/23/2003	Mark W. Rice	88066-5499	7526
28765	7590	07/31/2006	EXAMINER	
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006			MACNEILL, ELIZABETH	
		ART UNIT	PAPER NUMBER	
		3767		

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,436	RICE ET AL.	
	Examiner Elizabeth R. MacNeill	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12/23/2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s):

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/23/03, 10/18/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: In line to, the applicant refers to "an cartridge housing" This should be changed to "a cartridge housing". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 17 recites the limitation "the housing" in line 14. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 22 recites the limitation "the adapter" throughout this independent claim. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the claim language is unclear, specifically the wording "wherein the post position the post and cartridge housing are fixed together." Correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-12,16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by PEARSON (US #5,658,259).

Regarding claim 1, Pearson teaches "An injector filling assembly, comprising: an cartridge housing configured for receiving a first end of a cartridge (Fig 1 #12, Col 4 line 5) that has a chamber containing a medicament and first and second ends, the first end including a seal (Fig 1 #22, Col 4 line 19) for sealing the medicament in the chamber, and the second end including a stopper (Fig 1 #28, Col 4 lines 23-30) sealingly disposed in the chamber; an adapter associated with the cartridge housing (Fig 1 #11, Col 3 line 67) and configured for coupling the chamber to an injector for transferring the medicament to the injector; and a post (Fig 1 #28, Col 4 lines 23-30) associated with the cartridge housing in a post position from which movement towards the adapter is substantially prevented, wherein the post is configured such that positioning of the second end of the cartridge in a first position with respect to the post and of the post in the post position causes the post to displace the stopper towards the seal by an amount sufficient to overcome any adhesion between the chamber and the stopper for permitting filling of the injector from the chamber and for substantially preventing said movement of the cartridge past the first position."

Regarding claim 2, the post is insufficient to expel a substantial amount of fluid while in the first position (Fig 1 #28, Col 4 lines 23-30).

Regarding claim 3, the cartridge housing contains a cap (#204, Col 8 line 4).

Regarding claim 4, the cap receives the second end of the cartridge (#28, Col 4 lines 23-30).

Regarding claim 5, the engagement of the cap will displace any air contained in the cartridge (#28, Col 4 lines 23-30).

Regarding claim 6, engagement of the cap pushes the post into the first position (#28, Col 4 lines 23-30).

Regarding claims 7-10, the adapter has a needle cartridge-opening member with an adapter wall (#31) and the cartridge and injector in fluid communication (#34, Fig 3, Col 7 line 32-33)

Regarding claim 11, the housing and post are associated by a threaded connection (Fig 5 #206, Col 8 line 11)

Regarding claim 12, the adapter is configured to receive the first end of the cartridge (Fig 3 #100, Col 7 line 32).

Regarding claim 16, the post is associated with the cartridge housing in the post position for allowing the medicament to be aspirated from the chamber into the injector (Fig 1 #28, Col 4 lines 23-30).

Regarding claim 18, the assembly comprises a cartridge (Fig 12, Col 4 line 5).

8. Claims 1-12,16, and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by NELSON (US 2002/0007149)

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Nelson teaches "An injector filling assembly, comprising: an cartridge housing configured for receiving a first end of a cartridge (#20, P0034) that has a chamber containing a medicament and first and second ends, the first end including a seal (#22, P0034) for sealing the medicament in the chamber, and the second end including a stopper (#24, P0034) sealingly disposed in the chamber; an adapter associated with the cartridge housing (#12, P0032) and configured for coupling the chamber to an injector for transferring the medicament to the injector; and a post (#34, P0034) associated with the cartridge housing in a post position from which movement towards the adapter is substantially prevented, wherein the post is configured such that positioning of the second end of the cartridge in a first position with respect to the post and of the post in the post position causes the post to displace the stopper towards the seal by an amount sufficient to overcome any adhesion between the chamber and the stopper for permitting filling of the injector from the chamber and for substantially preventing said movement of the cartridge past the first position."

Regarding claim 2, the post is insufficient to expel a substantial amount of fluid while in the first position (#34, P0034).

Regarding claim 3, the cartridge housing contains a cap (#42, P0041).

Regarding claim 4, the cap receives the second end of the cartridge (#42, P0041).

Regarding claim 5, the engagement of the cap will displace any air contained in the cartridge (#34, P0034).

Regarding claim 6, engagement of the cap pushes the post into the first position (#34, P0034).

Regarding claims 7-10, the adapter has a needle cartridge-opening member with an adapter wall (#26, P0037) and the cartridge and injector in fluid communication (Fig 2, P0037)

Regarding claim 11, the housing and post are associated by a threaded connection (Fig 8 #90)

Regarding claim 12, the adapter is configured to receive the first end of the cartridge (Fig 1).

Regarding claim 16, the post is associated with the cartridge housing in the post position for allowing the medicament to be aspirated from the chamber into the injector (#34, P0034).

Regarding claim 18, the assembly comprises a cartridge (#20, P0034)

Regarding claim 20, the injection device is a needless injector is a nozzle (#29, plunger (#68), power pack (#14), housing (#42), trigger (#30) and energy source (66).

See paragraphs 0041-0042.

Regarding claim 21, the injector and filling assembly are connected by threaded portions (Fig 1 #40).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 17 rejected under 35 U.S.C. 103(a) as being unpatentable over PEARSON as applied to claims 1 and 18 above, and further in view of REINHARD (US #5,788,670), GENESE (US #4,171,698), and BROWN (US #2,717,601).

Pearson teaches an injector filling assembly and cartridge as described in claims 1 and 18, but does not disclose the use of a dual chamber cartridge.

Reinhard (Fig 1 #1, col 5 lines 36-47), Genese (Fig 1 #10, Col 2 lines 63-end), and Brown (Fig 1 #10, Col 1 lines 48-59) all disclose a dual chamber cartridge, with a first cartridge and a second cartridge separated by a dividing member and with a bypass chamber.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to replace the single chamber cartridge of Pearson with the dual chamber cartridge of Reinhard, Genese, or Brown in order to deliver the appropriate medicament to the patient.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pearson as applied to claim 1 above, and further in view of MARGULIES (US #4,333,458).

Pearson teaches the limitations of the injector filling assembly of claim 1, but does not teach a housing with a window. Marguiles teaches an injector housing with a window (Fig 1 #16, Col 4 line 13).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to construct the filling assembly of Pearson with the window of Marguiles to view the level of medicament remaining the fluid chamber.

12. Claims 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Pearson as applied to claims 1 and 3 above, and further in view of LUNDQUIST (US #5,807,309).

Regarding claim 13, Pearson teaches the limitations of the injector filling assembly of claims 1 and 3, but does not teach the frangible retaining member (Claim 13) for inhibiting the reuse of the filling assembly. Lundquist teaches a frangible retaining member (Fig 12 #132, Col 5 line 66), which prevents the reuse of the cartridge.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to construct the filling assembly of Pearson with the pin of Lundquist to prevent reuse of the filling assembly.

Regarding claim 14, Pearson teaches the limitations of the injector filling assembly of claims 1 and 3, but does not teach the plurality of resilient tabs. Pearson does teach a member (#43 (Col 7, line 14) and/or #243 (Col 8, line 62)) of the injector filling assembly which is in the same position and of the same

structure as the resilient tabs, but not of an appropriate material for breaking.

Lundquist teaches the use of frangible members to prevent reuse of an injector.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to construct the filling assembly of Pearson by replacing the material of the retaining tabs with the material of Lundquist to make the tabs breakable upon removal of the cartridge and therefore prevent reuse of the injector.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1, 3-10, 12-14, and 16-21 are rejected on the ground of nonstatutory double patenting over claims 1, 2, 6-10, 12-23 of U. S. Patent No. 6,673,035 since the

claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

Claim 1 of '035 reads on pending claim 20.

Claim 2 of '035 reads on pending claims 1,3,4,7,8,9, and 10.

Claim 6 of '035 reads on pending claim 1.

Claim 7 of '035 reads on pending claim 3.

Claim 8 of '035 reads on pending claims 3 and 6.

Claim 9 of '035 reads on pending claim 4.

Claim 10 of '035 reads on pending claim 5.

Claim 12 of '035 reads on pending claim 7.

Claim 13 of '035 reads on pending claim 8.

Claim 14 of '035 reads on pending claim 9.

Claim 15 of '035 reads on pending claim 10.

Claim 16 of '035 reads on pending claim 12.

Claim 17 of '035 reads on pending claim 13.

Claim 18 of '035 reads on pending claim 14.

Claim 19 of '035 reads on pending claim 16.

Claim 20 of '035 reads on pending claim 17.

Claim 21 of '035 reads on pending claim 18.

Claim 22 of '035 reads on pending claim 19.

Claim 23 of '035 reads on pending claim 21

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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